
From: "Martha M. Rumore" <mrumore@frierlevitt.com>
Sent: Fri 12/11/2020 5:41:29 PM (UTC)
To: "Danielle P. Manning" <DManning@frierlevitt.com>
Cc: Abbie Divilio <AbbieD@Safechain.com>
Subject: FW: Safe Chain Response to Gilead Letter of Nov 23 [GILEAD-LDMS.FID511078]
Attachment: Dec. 10, 2020 Reply Letter to Safe Chain Solutions LLC(4136679.1).pdf

Hi Danielle:

Could you file this under Safe Chain Solutions? Also, could you set up a meeting for Mon with the client?

Charles Boyd <CharlesB@Safechain.com>
Abbie Divilio AbbieD@Safechain.com

Tx,
Martha

Martha M. Rumore, PharmD, MS, JD, LLM
Senior Counsel

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GOVERNMENT
EXHIBIT

209

1:24-cr-20255-WPD

From: Peter Colosi <peter.colosi@gilead.com>
Sent: Thursday, December 10, 2020 6:22 PM
To: Martha M. Rumore <mrumore@frierlevitt.com>
Subject: RE: Safe Chain Response to Gilead Letter of Nov 23 [GILEAD-LDMS.FID511078]

[EXTERNAL SENDER: This message came from an EXTERNAL address. DO NOT click on links or attachments unless you know the sender and the content is safe.]

Martha –

Please see Gilead's reply to your Dec. 7 letter. Can I suggest a call to review the contents and get on the same page about what information Gilead is seeking? I'm fairly free next Monday if that works for you.

Pete Colosi (he/him/his)
415-341-3818

From: Martha M. Rumore <mrumore@frierlevitt.com>
Sent: Monday, December 7, 2020 1:46 PM
To: Peter Colosi <peter.colosi@gilead.com>
Subject: [EXTERNAL] Safe Chain Response to Gilead Letter of Nov 23

Dear Mr. Colosi:

Please see Safe Chain Solution's response to your November 23, 2020 letter.

Please let me know if you have any additional questions.

Very truly yours,

Martha M. Rumore, PharmD, MS, JD, LLM
Senior Counsel

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Anti-Counterfeiting

VIA EMAIL (mrumore@frierlevitt.com)

December 10, 2020

Martha M. Rumore, Pharm.D., Esq.
646-970-3226
mrumore@frierlevitt.com

Re: Sale of Counterfeit BIKTARVY® Lot # CCXKVA

Dear Ms. Rumore:

I am in receipt of your Dec. 7, 2020 letter (“Reply Letter”) responding to Gilead’s Nov. 23, 2020 letter regarding your client, Safe Chain’s purchase of illegitimate medicines bearing Gilead-owned trademarks outside of Gilead-authorized channels. I write to correct several misstatements in the Reply Letter and re-iterate Gilead’s requests for information related to Safe Chain’s actions. Our primary objective and concern is to identify the entity or entities that sold illegitimate product bearing Gilead trademarks to Safe Chain so that we can trace the product back up the chain in effort to identify the source.

BIKTARVY® Lot CDGXKA

First, regarding Safe Chain’s Oct. 5, 2020 request to verify certain DSCSA documentation (“T3 Document”), the T3 Document (attached) shows that, on Sep. 4, 2018, five units of BIKTARVY® Lot CDGXKA were purchased from Gilead by Rochester Drug Co-Op Inc. Safe Chain asked Gilead to confirm that this transaction between Gilead and Rochester Drug Co-Op took place. Just four days later, on Oct. 9, 2020 – not Nov. 9, 2020 as stated in the Reply Letter – Gilead emailed Safe Chain to state that the information on the T3 Document did not match Gilead’s records. The Reply Letter asserted, contrary to the plain text of Gilead’s Oct. 9 email, that Gilead “determined the product as illegitimate.” In fact, Gilead could not make any determination regarding any product, as we did not know whether the T3 Document related to a product in Safe Chain’s possession or control. We simply commented on the T3 Document’s veracity and stated that if the T3 Document did pertain to a product in Safe Chain’s possession, Safe Chain should quarantine any and all related products.

Apparently, the T3 Document did relate to a product, as the Reply Letter states that Safe Chain is currently quarantining multiple bottles of Lot CDGXKA. Gilead’s Oct. 9 notification that the T3 Document was fraudulent should have triggered Safe Chain’s Drug Supply Chain Security Act obligations to not just quarantine any products related to that T3 Document¹, but also its obligation to notify the FDA that it was in possession of illegitimate product². Contrary to the Reply Letter’s baseless statement, Gilead was under no obligation to notify the FDA as Safe Chain is not an “immediate trading partner” as defined by the DSCSA.³ Nonetheless, Gilead is happy to notify

¹ See 21 U.S.C. § 360eee-1(c)(4)(B)(i)(I).

² See 21 U.S.C. § 360eee-1(c)(4)(B)(ii).

³ See 21 U.S.C. § 360eee-1(b)(4)(B)(ii)(II) and 360eee(23) (definition of “trading partner”).

FDA OCI about Safe Chain's purchase of illegitimate product outside of the Gilead-authorized supply chain, Safe Chain's failure to meet its DSCSA obligations, and request that FDA confiscate all quarantined product.

BIKTARVY® Lot CCXKVA

Next, regarding Safe Chain's admitted sale of BIKTARVY Lot CCXKVA to White Cross, that product was inspected by Gilead and determined to bear counterfeit Gilead-owned trademarks, as referenced in the Nov. 23 letter. That letter asked Safe Chain to confirm the invoice White Cross provided to Gilead was real, which it did, and for Safe Chain to cooperate with Gilead's investigation by providing us its supplier for the counterfeit product, which it did not.

Gilead reiterates its request for Safe Chain's source of the Lot CCXKVA BIKTARVY it sold to White Cross. Safe Chain's response that it purchased the Lot CCXKVA BIKTARVY "from an authorized trading partner" is wholly inadequate. Gilead is simply attempting to determine how this illegitimate product made its way into the supply chain. We do not understand Safe Chain's reluctance to cooperate with this investigation.

FDA Recalls

Lastly, in both matters, the Reply Letter wrongfully implies that Gilead has some obligation to recall the medicines at issue. Here, the facts of each case demonstrate only that these are two instances of Safe Chain purchasing illegitimate medicines outside of Gilead-authorized supply chains. In neither case did Gilead manufacture these medicines as either the bottle contained foreign tablets (as in the case of the Lot CCXKVA BIKTARVY) or the pedigree documentation associated with the medicine was fraudulent (as in the case of the Lot CDGXKA BIKTARVY).

This letter is without prejudice to any rights and remedies of Gilead, all of which are expressly reserved. I look forward to a response and the requested information no later than December 18, 2020.

Sincerely,

Peter M. Colosi

Peter M. Colosi
Senior Counsel, Anti-Counterfeiting
Gilead Sciences, Inc.
Peter.colosi@gilead.com
650-389-8733

SAFE CHAIN SOLUTIONS, LLC

Drug Supply Chain Security Act Document

(TI) Transaction Information

Drug Name, Strength, Dosage Form, Container Size: BIKTARVY 30CT			Reference Number: <u>INV 6901</u> Document Type: <u>INVOICE</u> Reference Date: <u>09/28/2020</u>											
NDC: 61958-2501-01														
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Lot Number</th> <th style="text-align: left;">Quantity</th> <th style="text-align: left;">Unique Serial #</th> </tr> </thead> <tbody> <tr> <td>CDGXKA</td> <td>5</td> <td></td> </tr> <tr> <td> </td> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>	Lot Number	Quantity	Unique Serial #	CDGXKA	5									
Lot Number	Quantity	Unique Serial #												
CDGXKA	5													

(TH) Transaction History

Manufacturer's Name: Gilead Sciences, Inc.
Manufacturer's information: 333 Lakeside Drive, Foster City, CA 94404

SOLD TO: Name: Rochester Drug Co-Op Inc Address: 116 Lehigh Dr #3013 Fairfield, NJ 07004 Date Purchased & Ref : 09/04/18 PO#R2367	SHIPPED TO: Name: Rochester Drug Co-Op Inc Address: 116 Lehigh Dr #3013 Fairfield, NJ 07004 Date Received & Ref : 09/04/18
SOLD TO: Name: Instacare Pharmacy DBA Brookville RX Address: 235-20 147th Ave Rosedale, NY 11422 Date Purchased & Ref : 10/15/18 PO#001IC545	SHIPPED TO: Name: Instacare Pharmacy DBA Brookville RX Address: 235-20 147th Ave Rosedale, NY 11422 Date Received & Ref : 10/15/18
SOLD TO: Name: BOULEVARD 9229 LLC Address: 9229 QUEENS BLVD STE 11 REGO PARK, NY 11374 Date Purchased & Ref : 09/15/20 PO#01209744	SHIPPED TO: Name: BOULEVARD 9229 LLC Address: 9229 QUEENS BLVD STE 11 REGO PARK, NY 11374 Date Received & Ref : 09/15/20
SOLD TO: Name: SAFE CHAIN SOLUTIONS, LLC Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Purchased & Ref : 09/28/20 PO#9311	SHIPPED TO: Name: SAFE CHAIN SOLUTIONS, LLC Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Received & Ref : 09/28/20
SOLD TO: Name: Address: Date Purchased & Ref :	SHIPPED TO: Name: Address: Date Received & Ref :

(TS) Transaction Statement: This Company complied with each applicable subsection of FDCA Sec. 581 (27) (A) – (G)

- (A) is authorized as required under the Drug Supply Chain Security Act;
 (B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;
 (C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;
 (D) did not knowingly ship a suspect or illegitimate product;
 (E) had systems and processes in place to comply with verification requirements under section 582;
 (F) did not knowingly provide false transaction information; and
 (G) did not knowingly alter the transaction history.